

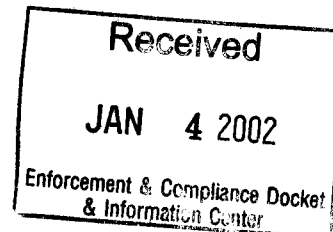
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THOMAS ASSOCIATES, INC., EXECUTIVE SECRETARY

CFFA

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United States Environmental Protection Agency
Enforcement and Compliance Docket & Information Center
Mail Code 2201A
Attn: Docket Number EC-2000-007
1200 Pennsylvania Avenue NW
Washington, DC 20460

Ladies and Gentlemen:

CFFA is a non-profit trade Association whose members manufacture chemical fabrics and film used in numerous applications such as automotive interiors, wallcoverings and upholstery.

EPA recently published a proposed rule on electronic reporting and electronic recordkeeping, the Cross-Media Electronic Reporting and Recordkeeping Rule ("CROMERRR"), 66 Fed. Reg. 46162 (Aug. 31, 2001). Its purpose is to allow electronic reporting by regulated entities to EPA (or to state and tribal entities implementing EPA requirements), and to allow regulated entities to keep EPA-mandated records electronically.

While the electronic reporting and electronic signature provisions are of interest, the electronic recordkeeping aspects are of considerable concern to CFFA and our member companies. The basic concern is that, while presented as voluntary, they in effect appear to be mandatory for the wide range of information currently stored electronically by our member companies. Any use of computers to generate or store data needed to meet EPA recordkeeping requirements would appear to trigger CROMERRR's very stringent anti-fraud provisions.

With respect to electronic recordkeeping, CROMERRR seems to have two important impacts on our members:

- CROMERRR appears to take the position that current practices using data stored on computers to meet EPA recordkeeping requirements are impermissible.
- CROMERRR appears to take the position that future use of computers to store data for EPA recordkeeping requirements would be permissible only if, in most cases, very expensive retrofits for existing computer systems or new computer systems are purchased. For example, Microsoft Excel® lacks an audit trail capability, but such a capability would be required by CROMERRR.

Discussion of CFFA Concerns

1. Although EPA presents the CROMERRR recordkeeping provisions as voluntary, its text suggests that they would be mandatory for almost all uses of computers to store data intended to meet EPA recordkeeping requirements. This appears to mean that, as a practical matter, most or all entities subject to EPA recordkeeping requirements would be required to comply with the CROMERRR recordkeeping requirements. That in turn would mean that they would have to adapt their computer systems to meet CROMERRR requirements.

2. CROMERRR seems to take the position that the use of electronic means to store data intended to meet EPA recordkeeping requirements is now impermissible and will remain impermissible until EPA announces that such use of computers is permissible.
3. The CROMERRR recordkeeping provisions would seem to impose very high costs on facilities, potentially in the millions of dollars, and well in excess of the \$40,000 per facility estimated in the preamble. The technical demands are considerable.
4. In proposing CROMERRR, EPA seems to have endorsed a "one size fits all" approach to electronic recordkeeping and particularly to the anti-fraud requirements. It apparently did not conduct a risk assessment or cost-benefit analysis on the need for such stringent anti-fraud provisions, although directed by OMB to do so. OMB guidance suggests that a risk assessment and cost-benefit analysis might indicate that EPA may not need CROMERRR's strong anti-fraud provisions.

Definition Of Electronic Record & Applicability To Current Recordkeeping

The key definition contained in the proposal is that of "electronic record". Proposed § 3.3 would define that term as:

"any combination of text, graphics, data, audio, pictorial, or other information represented in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system."

This broad definition would appear to encompass both records kept electronically at all times and those created or stored temporarily on a computer, then later printed out.

Qualifying as an "electronic record" means that information kept electronically to meet an EPA recordkeeping requirement would be subject to the provisions of Subpart C of proposed Part 3. As discussed below, those provisions would entail substantial costs. Proposed § 3.100(a) would provide in part:

"An electronic record . . . will satisfy a recordkeeping requirement of an EPA-administered environmental program under this Title [i.e., 40 CFR] **only** if it is generated and maintained by an acceptable electronic record-retention system as specified under this subsection."

Where regulated entities routinely store monitoring data, emissions data, or other information on a computer, such storage would apparently subject the regulated entities to all of the CROMERRR requirements for electronic recordkeeping; there would seem to be nothing "voluntary" about those requirements.

Where regulated entities routinely maintain required information on a computer, then periodically print out that data, the printed copy apparently would not be sufficient to avoid the application of CROMERRR. A paper copy would present data that at least at some point would have been created or modified or maintained or archived by a computer system, and therefore qualified as an electronic record.

Accordingly, CROMERRR is apparently not really "voluntary" at all. In today's electronic age, most regulated entities would seem to have no choice but to collect and store data on a computer, and that would seem to be enough to make CROMERRR recordkeeping provisions apply. The result would be that all or most of our member companies subject to EPA recordkeeping requirements would have to adapt their computer systems to meet CROMERRR requirements.

CROMERRR Cost Concerns

It appears that CROMERRR imposes requirements for substantial anti-fraud provisions that most current computer systems simply do not have. These requirements apply both to new systems and to existing systems. There would apparently be no grandfathering of legacy systems under CROMERRR.

CROMERRR appears to have the following core requirements, among others:

- Generate and maintain accurate and complete electronic records in a form that may not be altered without detection.
- Maintain all electronic records without alteration for the entirety of the required period for record retention. ~~While many EPA recordkeeping requirements have retention periods of five years or less, some have longer periods.~~ For example, the record retention period for the FIFRA Good Laboratory Practice regulations is for the life of the pesticide registration, which could last decades. Given the changes in both software and hardware that will occur over time, maintaining legacy systems or transitioning the data accurately across multiple generations of computer systems is very difficult.
- Produce accurate and complete copies of any electronic record and render these available, in both human readable and electronic form, for on-site inspection and off-site review, for the entirety of the record retention period. This means that EPA would be authorized to access a regulated entity's computer system and search it.
- Use secure, computer-generated, time-stamped audit trails that automatically record the date and time of operator entries and actions that create, modify, or delete electronic records. Many computer systems and software lack this capability. For example, Microsoft Excel® lacks an audit trail capability, and apparently could not be used without an expensive (and potentially problematic) add-on feature.
- Ensure that record changes do not obscure previously recorded information and that audit trail information is retained for at least the record retention period to be available for agency review.
- Archive electronic records in an electronic format which preserves the context, meta data, and audit trail. If necessary, ensure that complete records can be transferred to a new system including related meta data.

~~These are very challenging requirements, as recognized by federal agencies considering adoption of such requirements for their internal records.~~

In summary, CROMERRR raises a number of significant concerns for our member companies. At a time when most of our member companies routinely maintain electronic records for a wide range of EPA required reports and compliance demonstrations, the proposed rule has a potentially enormous impact on our member companies. We respectfully submit that an extensive rulemaking of this sort should be undertaken only after a thorough risk assessment and cost benefit analysis (regarding the strict anti-fraud provisions) following OMB guidance.

Very truly yours,



JOHN FINN
Chairman - CFFA Environmental Committee

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